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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/599,400	06/22/00	SAVITZKY K	24286

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EXAMINER	
PRASAD,S	
ART UNIT	**PAPER NUMBER**
1646	16

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/599,400	Savitzky et al.	
	Examiner	Art Unit	
	Sarada C Prasad	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Detailed Action

1. Applicant's election with traverse of Group I (with SEQ ID NO:9, claims 1-2, 5, 9-15) in Paper No. 15 (3/12/01) is acknowledged.

2. New claim 38 of Paper No. 15 (3/12/01) has been entered.

3. The restriction requirement of Paper No. 11 (2/8/01) has been reconsidered in light of the claims 12-15 directed to gene therapy as part of the elected invention (Group I), and restriction to the following inventions has been reconstructed as follows:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I-VIII: Claims 1-2, 5, 9-11, 38, drawn to a splicing variant of tumor necrosis factor Receptor protein, an expression vector, and a host cell, classified in class 536, subclass 23.5.

Group IX-XVI: Claims 3-4, 31, 32 drawn to a splicing variant of tumor necrosis factor receptor protein, classified in class 530, subclass 350.

Group XVII-XXIV: Claims 6-8, 34, 35, 36, 37 drawn to an antibody to a splicing variant of tumor necrosis factor receptor protein, and quantuitating the amount of protein, classified in class 530, subclass 387.1.

Group XXV-XXXII: Claims 16-17, 18-21, drawn to a method of detecting the presence of a nucleic acid encoding a splicing variant of tumor necrosis factor receptor protein in a sample classified in class 435, subclass 6.

Group XXXIII-XXXX: Claims 22-24, drawn to a method of identifying candidate compounds capable of binding a splicing variant of tumor necrosis factor receptor protein, classified in class 435, subclass 7.1.

Group XXXXI-XXXXVIII: Claim 25, drawn to an agonist of a splicing variant of tumor necrosis factor receptor protein, class and subclass undeterminable.

Group XXXXIX-LVI: Claim 26, drawn to an antagonist of a splicing variant of tumor necrosis factor Group receptor protein, class and subclass undeterminable.

Group LVII-LXIV: Claims 27-30, drawn to a method of determining a splicing variant of tumor necrosis factor receptor protein in a sample using an antibody, classified in class 435, subclass 7.1.

Group LXV-LXXII: Claims 12-15, 33 drawn to pharmaceutical compositions for gene therapy, classified in class 514, subclass 44.

Applicants are advised that claims 12-15 are improper Markush claims because the multiple elements recited therein are polypeptides, antibodies and nucleic acids, which do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. These polypeptides, antibodies and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art polypeptides or nucleic acids.

Inventions I-LXXII, are distinct, each from the other because of the following reasons:

Inventions I-VIII, IX-XVI and XVII-XXIV are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Groups I-VIII can be used to make a hybridization probe or can

be used in gene therapy as well as in the production of the protein of interest. The protein of Group IX-XVI can be used other than to make the antibody of Group XVII-XXIV, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group XVII-XXIV can be used to obtain the nucleic acid of Groups I-VIII, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically.

Inventions I-VIII and XXV-XXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions I-VIII can be used in recombinant production of the protein of interest, or hybridization probes, or diagnosis, while detection of nucleic acid is carried out by hybridization.

Inventions XVII-XXIV and LVII-LXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention XVII-XXIV can also can be used in immunoaffinity chromatography.

Inventions IX-XVI and XXXIII-XXXX and are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide products of inventions IX-XVI can also can be used as antigen in the production of antibodies.

Inventions I-VIII, XXXVII-LXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IX-XVI, XXV-XXXVI, XXXXIII-LXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XVII-XXIV and XXXV-LVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XXXXIII-XXXXVIII and XXV-XXXXII, LVII-LXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different

effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XXXXIX-LVI and XXV-XXXXII, LVII-LXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XXV-XXXXII and LVII-LXIV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Inventions I-VIII and LXV-LXXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the pharmaceutical compositions nucleic acids of inventions LXV-LXXII can be used for in vivo administration such as for gene therapy, while the nucleic acids of inventions I-VIII can be used as hybridization probes, or for encoding the corresponding polypeptides. Therefore, these inventions the different inventions are not disclosed as capable of use together.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
May, 16th, 2001

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER